

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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HIBERG A/S St. Kongensgade 59A DK-1264 Copenhagen K DANEMARK	12 JULI 2004 HØIBERG

PCT

WRITTEN OPINION  
(PCT Rule 66)

Applicant's or agent's file reference P688PC00		Date of mailing (day/month/year) 08.07.2004
International application No. PCT/DK 03/00686	International filing date (day/month/year) 10.10.2003	Priority date (day/month/year) 11.10.2002
International Patent Classification (IPC) or both national classification and IPC A61L27/44		
Applicant CARTIFICIAL A/S et al.		

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.
 

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bts. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 11.02.2005

Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Pilling, S <hr/> Formalities officer (incl. extension of time limits) Ladurner, Y Telephone No. +49 89 2399-7913
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**I. Basis of the opinion**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-49 as originally filed

**Claims, Numbers**

1-101 as originally filed

**Drawings, Sheets**

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5.  This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1,56 (YES)
Inventive step (IS)	Claims	1,56 (NO)
Industrial applicability (IA)	Claims	

**2. Citations and explanations**

**see separate sheet**

Re Item VReasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D6 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
2. None of the presently available prior art documents disclose a medical device comprising the layered structure defined in either present Claim 1 or Claim 56. Thus, the subject matter of Claims 1 and 56 is new (Article 33(2) PCT). *artificial lans.*  
*WO0145595*
3. The closest prior art in respect of Claims 1 and 56 appears to be document D1 since this document discloses a biocompatible prosthetic device for insertion into a joint cavity comprising a first polymeric component and a second shorter chain length polymeric component (see page 2 lines 2 to 7 in D1). These layers are disclosed to have different physical properties facilitating the function of the device as a joint spacer (see page 10 lines 20 to 28 in D1). The first polymeric component is said to confer tensile strength (see page 17 lines 7 to 9 in D1) while the second polymeric component contributes the necessary resilient properties (see page 18 lines 7 to 10 and also page 18 lines 22 to 25 in D1).
4. Thus, the difference between the medical device of document D1 and the medical device set out in present Claims 1 and 56 is the present additional provision of a further (upper or lower) layer comprising a third polymeric component having a chain length longer than the previously mentioned second polymeric component (see the previous paragraph). On the basis of the present description it appears that the additional provision of this third polymeric component contributes to the tensile strength/wear resistance of the present device (see present page 9 lines 4 to 12). Thus the objective technical problem to be solved by the subject matter of the present invention is "how to increase the tensile strength of medical devices
5. Document D1 discloses that the first polymeric component (with a longer chain length) increases the tensile strength of the device (see page 17 lines 7 to 9 in D1). Thus, it is considered that the provision of a further layer of this first polymeric component as defined in present Claim 1 and 56 in order to increase the tensile strength of the device of document D1 would be obvious to one of skill in this art.  
? The technical effects, i.e. increased tensile strength, of providing such a further

layer are explicitly indicated in document D1.

6. It is further noted that document D1 even indicates that the prosthetic device may comprise a third polymeric component. Thus the subject matter of present Claims 1 and 56 appears particularly obvious.
7. Should the Applicant choose to submit amended pages to the IPEA in order to overcome the objections listed herein above, then the Applicant is requested to identify each amendment made and to indicate the support for each amendment in the originally filed specification (Rule 66.8 PCT). If this action is not carried out then the IPEA may decide not take the amendments into account and the IPER may be drafted on the basis of the present application documents.
8. The attention of the Applicant is also drawn to the fact that if the application contains an unjustified plurality of independent claims then no examination of any of the claims will be carried out.